

K 120438

MAY - 2 2012

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

Submitter

Company:3M Deutschland GmbH
Street:ESPE Platz
ZIP-Code, City:D-82229 Seefeld
Federal State:Bavaria
Country:Germany
Establishment Registration Number9611385
Official Correspondent:Dr. Desi W. Soegiarto,
.....Regulatory Affairs Specialist
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Date:February 10, 2012

Name of Device

Proprietary Name:Flash (different materials):
Flash Penta™ HB SQ
Flash Penta™ HB Q
Flash Heavy Body SQ
Flash Heavy Body Q
Flash Regular Body SQ
Flash Regular Body Q
Flash Light Body SQ
Flash Light Body Q
Flash Ultra-Light Body SQ
Flash Penta™ Putty

Classification Name:.....Impression material

Common Name:Dental impression material

Predicate Devices

Future Wash/YPS by 3M Deutschland GmbH, Germany K051797

Dimension Penta H by 3M Deutschland GmbH, Germany K000591

3M ProPlus System by 3M ESPE Dental Products, U.S.A. K963766

Description for the Premarket Notification

Flash materials are classified as impression materials (21 C.F.R. § 872.3660) because they are devices intended to reproduce the structure of a patient's teeth.

Flash will be available as wash and tray materials. The wash materials will be available in one viscosity (light-bodied), each of them in a regular set and a super-quick set version. The tray materials will be available in two different viscosities (putty and heavy-bodied) in a regular set and a super-quick set version.

As the predicate devices, Flash materials are two component (base paste/catalyst) vinyl polysiloxane impression materials designed either to be used in 3M Deutschland GmbH's mixing, dosing and dispensing device, Garant™, or to automatically be mixed and dispensed in the Pentamix™ device of 3M Deutschland GmbH.

In this 510(k) premarket notification Flash has been compared to the predicate devices with regard to indications for use, physical and mechanical properties, and chemical composition. The comparison for indications for use, performance data, and chemistry shows that Flash is substantially equivalent to the predicate devices.

Biocompatibility testing was carried out. Biocompatibility assessments were developed for Flash using standard risk assessment techniques and consideration of FDA & internationally recognized guidelines. The conclusion of the assessments is that Flash materials are biocompatible for its intended use.

In summary, it can be concluded that Flash is as substantially equivalent in safety and effectiveness as the predicate devices Future Wash/YPS by 3M Deutschland GmbH, Germany (K051797), Dimension Penta H by 3M Deutschland GmbH, Germany (K000591), and 3M ProPlus System by 3M ESPE Dental Products, U.S.A. (K963766).

Indications for Use:

Flash VPS Impression Materials are indicated to be used for all precision impressions (of e.g.: crown, bridge, inlay and onlay preparations).



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room - WO66-G609
Silver Spring, MD 20993-0002

Dr. Desi W. Soegiarto
Regulatory Affairs Specialist
3M Deutschland GmbH
ESPE Platz
D-82229 Seefeld
GERMANY

MAY - 2 2012

Re: K120438
Trade/Device Name: Flash
Regulation Number: 21 CFR 872.3660
Regulation Name: Impression Material
Regulatory Class: II
Product Code: ELW
Dated: February 10, 2012
Received: February 13, 2012

Dear Dr. Soegiarto:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,



Anthony D. Watson, B.S., M.S., M.B.A.

Director

Division of Anesthesiology, General Hospital,

Infection Control and Dental Devices

Office of Device Evaluation

Center for Devices and

Radiological Health

Enclosure

Indications for Use

510(k) Number (if known):

K120438

Device Name:

Flash

Indications For Use:

Flash VPS Impression Materials are indicated to be used for all precision impressions (of e.g.: crown, bridge, inlay and onlay preparations).

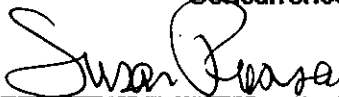
Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF
NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)



(Division Sign-Off)

Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

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510(k) Number: _____

K120438